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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,590	01/09/2002	Michel G.M. Perbost	10991396-2	6342

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[REDACTED] EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
	1639

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/043,590	PERBOST ET AL.
	Examiner	Art Unit
	My-Chau T. Tran	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 29-37 is/are pending in the application.
- 4a) Of the above claim(s) 36 and 37 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 29-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 29-35) in Paper Dated 10/10/2003 is acknowledged.

The traversal is on the ground(s) that Group I (Claims 29-35) and Group II (Claim 36) be rejoined because both Group I and Group II use the same non-miscible fluid (NMF). This is not found persuasive because although both Group I and Group II use the same type of compound (e.g. non-miscible fluid (NMF)) their method of use for this compound is distinct from each other. Group I use the NMF as an additional layer on the surface of the substrate and link the biopolymer to the surface. Group II use the NMF as a “shield” to protect the reactants in a synthesis reaction. Therefore, Group I is not rejoined with Group II.

The traversal is on the ground(s) that Group III (Claim 37) and Group I (Claims 29-35) be rejoined because “[I]t is unclear to Applicant how using the claimed product in “the process of coating a metal substrate” is a materially different process of using the product from the process claimed in the Group I Invention”. This is not found persuasive because the method claimed in Group I, which is *a method of fabricating a biopolymer array*, would include an additional reagent (i.e. biopolymer) and produced a different product than the process of coating a metal substrate (e.g. does not require any additional reagent and produce a different product such a painted metal sheet). Therefore, Group III is not rejoined with Group I.

The traversal is on the ground(s) that Group III (Claim 37) and Group II (Claim 36) be rejoined because “[A]pplicant submits that using the claimed product in “the process of coating a metal substrate” is not a materially different process of using the product from the process

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claimed in the Group II Invention". This is not found persuasive because the method claimed in Group II, which is *a method of shielding biosynthesis reactions and sensitive biosynthesis reactants from the ambient environment*, would include an additional reagents (i.e. biopolymers) and produced a different product than the process of coating a metal substrate (e.g. does not require any additional reagent and produce a different product such a painted metal sheet). Additionally, it is unclear how applicant equate that a metal substrate is synonymous with a biosynthesis reactions and sensitive biosynthesis reactants. Therefore, Group III is not rejoined with Group II.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 36 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper Dated 10/10/2003.

3. Claims 29-35 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claim 29 recites a method of fabricating a biopolymer array from pre-synthesized biopolymers. The method step comprises adding a non-miscible fluid (NMF) to the array surface, the NMF being inert, immiscible and insoluble in aqueous solution; and depositing the biopolymer solution on the array surface and linking the biopolymer to the surface.

The specification disclosure does not sufficiently teach the method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the first step is to “enclose” the surface of the array with a non-miscible fluid (NMF) and then adding the biopolymer solution onto the array surface to link the biopolymer to the surface. Since the NMF is inert, immiscible and insoluble in aqueous solution, it would prevent the “attachment” of the biopolymer to the surface.

The specification description is directed to a method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the droplets of the deprotected pre-synthesized biopolymer solution is enclosed in the NMF before depositing onto the array surface (pg. 7, lines 8-20). This method clearly does not provide an adequate representation regarding adding the biopolymer solution on “top” of the NMF. The specification does not teach the method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the first step is to cover the surface of the array with a non-miscible fluid (NMF) and then adding the biopolymer solution onto the array surface, which would link the biopolymer to the surface.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of the method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the droplets of the deprotected pre-synthesized biopolymer solution is enclosed in the NMF before depositing onto the array surface disclosed by the specification, the skilled artisan cannot envision the method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the array surface is first "enclosed" with a non-miscible fluid. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams,

formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the claimed method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the array surface is first "enclosed" with a non-miscible fluid. The specification does not teach the method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the first step is to cover the surface of the array with a non-miscible fluid (NMF) and then adding the biopolymer solution onto the array surface, which would link the biopolymer to the surface. Therefore, only the method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the droplets of the deprotected pre-synthesized biopolymer solution is enclosed in the NMF before depositing onto the array surface, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. It is unclear as to how the biopolymer is link to the surface when the surface is "cover" with the non-miscible fluid (NMF) as claimed in claim 29 because as define in the specification (pg. 19, line 10-11) that "*the NMF does not chemically react with the biomonomer, reagents, anhydrous solvent or other ancillary materials*" (e.g. inert).

b. It is unclear how the biopolymer solution is deposited on the array surface **through** the NMF as claimed in claims 30, 32, and 34-35 because as define in claim 29 the NMF is immiscible and insoluble in aqueous solution.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US Patent 5,063,081).

Cozzette et al. disclose a manufacturing method for producing a biosensor (biopolymer array) wherein the biosensor comprise of layered structures in which one or more biologically active species are immobilized (col. 19, lines 23-45). The method steps comprise of adding a solution of silane mixture (non-miscible fluid (NMF)), which is aqueous as well as water-miscible organic solvent (col. 28, lines 19-23), that form a layer of permselective membrane (col. 13, lines 54-62; col. 29, lines 39-43); and a step of immobilizing the biological active species onto the surface to form an array of biopolymer (col. 31, lines 21-30). Therefore, the method of Cozzette et al. anticipates the presently claimed method.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

mct
January 7, 2004



PADMASHRI PONNALURI
PRIMARY EXAMINER